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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,505	04/22/2004	Shan X. Wang	S00-163/US	6970

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EXAMINER	
DO, PENSEE T	
ART UNIT	**PAPER NUMBER**
1641	
MAIL DATE	**DELIVERY MODE**
06/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,505	WANG ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *20-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/06/2005; 10/27/04; 04/22/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of group I, claims 1-19 in the reply filed on February 27, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method of detecting a molecule of interest in the preamble. However, the body of the claim fails to recite a step of detecting such molecule of interest. It is also unclear which molecule, first or second, is the molecule of interest.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

> 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-8, 10, 11, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Fox (WO 01/14591, published March 1, 2001).

Fox teaches a method of detecting a molecule of interest, the method comprises providing a first molecule bonded to a magnetizable nanoparticle; providing a second molecule bonded to a substrate; contacting the first molecule with the second molecule to promote binding between the two molecules to form a complex; detecting the complex. (see pg. 20, lines 15-18; pg. 6, lines 15-20). For claims 2-8, Fox teaches that the target molecule/specific binding molecule (first molecule or second molecule respectively) are among proteins (antigens/antibodies), polypeptides, nucleic acids (see pg. 11, lines 14-15; pg. 20, lines 14-15; pg. 21, lines 6-7). For claims 10-11, Fox teaches that the magnetic particles are ferromagnetic, ferrimagnetic, paramagnetic or superparamagnetic. (see pg. 8, lines 20-23). Fox teaches using a sensitive giant

magnetoresistive ratio sensor (GMR) to detect the complex. The GMR sensor advantageously includes biasing magnets for producing an applied biasing magnetic field. The input voltage and the output sensor are routed to an operational amplifier and the output signal (net signal) is measured. This output signal will vary with the intensity of the an externally applied magnetic field. (for claims 17 and 19). (see pg. 13, line 25-pg. 14, line 10).

Claims 1-8, 10, 11, 14-17, 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Coehoorn et al. (WO 03/054523, published July 3, 2003).

Coehoorn teaches a method of magnetic detection comprising providing biological molecules on a substrate of a magnetoresistive device; adding magnetic nanoparticles conjugated with binding molecules specific for the biological molecules on the substrate of the magnetoresistive device so that the biological molecules on the substrate and the nanoparticles form a complex; detecting such complex. (see abstract; pg. 5, lines 18-30). For claims 2-8, Coehoorn teaches the molecules are DNA, RNA, proteins (antigens or antibodies), or peptides, etc. (see pg. 8, lines 3-20). For claims 10 and 11, Coehoorn teaches that the magnetic nanoparticles are superparamagnetic . For claims 14 and 15, Coehoorn teaches that the magnetic nanoparticles diameter range between and 250 nm, preferably between 3 and 100 nm, or 10 and 60 nm. (see pg. 5, lines 28-36). For claim 16, Coehoorn teaches using a spin-valve substrate. (see table on pg. 23). For claims 17 and 19, Coehoorn teaches an external magnetic field is applied and a net signal generated by the magnetic field in the plane of the GMR elements is detected. (see pg. 11, lines 17-19; pg. 11, lines 28-33).

Claims 1, 2-8, 10, 11, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Baselt (US 5,981,297, Nov. 9, 1999).

Baselt teaches a method for detecting target molecules. The method comprises providing a recognition molecules bound to a surface of a magnetic field sensor; adding target molecules bound to magnetic particles; exposing the magnetic particles bound target molecules to the surface of the magnetic field sensor bound recognition molecules so that the molecules form a complex; detecting such complex. (see col. 3, lines 39-59). For claims 2-8, Baselt teaches that the recognition molecules or the target molecules are peptides, antibodies, DNA or RNA, proteins, etc. (see col. 4, lines 3-7). For claims 10 and 11, Baselt teaches that the magnetic particles are superparamagnetic (see col. 3, lines 60-65). For claim 17, Baselt teaches applying an external magnetic field to detect the complex. (see col. 7, lines 25-30). For claim 19, Baselt teaches detecting a net signal or resistance change in the magnetoresistive element. (see col. 8, lines 8-24).

Claims 1-8, 10, 11, 14, 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Terstappen et al. (US 6,623,983, September 23, 2003).

Terstappen teaches a method for immobilizing magnetically labeled particulate entities on a collection surface via binding between specific binding pair members. The method comprises providing one member of a specific binding pair bound to the collection surface and the other member bound to magnetic nanoparticles; exposing the magnetic nanoparticles bound binding member to the collection surface to form a complex between the binding members; detecting said complex. (see col. 6, lines 18-

50;col. 12, lines 53-57). For claims 2-8, Terstappen teaches the binding members are proteins (antibodies, antigens, peptides,) or RNA or DNA. (see col. 8, lines 50-55; col. 9, lines 20-25; col. 10, lines 29-30). For claims 10 and 11, Terstappen teaches that the magnetic nanoparticles are superparamagnetic. (see col. 2, lines 42-44). For claims 14 and 15, Terstappen teaches the diameter of the magnetic nanoparticles range from 20-25 nm (see col. 2, line 53) or less than 200 nm. (see col. 9,line 64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox, or Baselt or Coehoorn in view of Berning et al. (PGPub US 2005/0025969).

Fox, Baselt and Coehoorn have been discussed above.

However, they fail to teach that the first molecule is covalently bonded to at least one magnetizable nanoparticle by a gold-thiol linkage, and the nanoparticle comprises a noble metal surface layer such as a gold surface layer.

Berning teaches nanoparticles coated with a layer of gold including a magnetic nanoparticle central core, and a coating of gold completely encapsulating the magnetic nanoparticle central core. The composite further comprises thiol-bound functional group-containing spacer groups thereon the gold-coated magnetic nanoparticles. (see [0009]. The gold-coated magnetic nanoparticles are further coupled to recognition group

such as proteins, peptides, nucleic acids, (see [0014]. The size of the magnetic nanoparticles range from 10 nm to 250 nm. (see [0011]).

It would have been obvious to one of ordinary skills in the art to use the magnetic nanoparticles coated with a gold surface layer and thiol group as taught by Berning the method of Fox, Baselt or Coehoorn because such gold-coated magnetic nanoparticles of Berning would prevent direct bio-contact to the magnetic material thus improving biocompatibility. A gold surface also allows good coupling through chemical attachment of binding agents or recognition agents such as peptides, proteins or nucleic acids. (see Berning [0010]).

Claims 16, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox or Baselt in view of Li et al. (Journal of Applied Physics May 15, 2003).

Fox and Baselt have been discussed above.

However, Fox and Baselt fail to teach the substrate comprises a high sensitivity spin valve or a magnetic tunnel junction detection array; and detecting comprises applying a DC bias field and an AC tickling field.

Li teaches using highly sensitive spin valve sensors to detect the presence of a superparamagnetic bead in DNA fragment detection. Li teaches using nanoparticles such as superparamagnetic bead of size 11 nm (see abstract) as markers of biomolecules and GMR elements detect the presence of the particles that were immobilized to the sensors through the intermolecular interactions, e.g. DNA hybridization. The method of detecting the magnetic particles includes applying a DC bias field and an AC tickling field. (see pg. 7558, first paragraph, fig. 2).

Since Fox and Baselt teaches using GMR elements, it would have been obvious to one of ordinary skills in the art to use the spin valve element of GMR as taught by Li with the application of a DC bias field and an AC tickling field to detect magnetic beads since spin valve-type GMR is a highly sensitive magnetic sensor element which exhibits a high-signal to noise ratio of output and stable operation.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coehoorn in view of Li et al.

Coehoorn has been discussed above.

However, Coehoorn fails to teach applying a DC bias field and an AC tickling field for detecting the magnetic particles.

Li et al. has been discussed above for teaching spin valve sensor and applying DC bias field and AC tickling field.

It would have been obvious to one of ordinary skills in the art to apply a DC bias field and an AC tickling field as taught by Li to detect the magnetic particles in the method of Coehoorn since Coehoorn teaches using a spin-valve sensor element in the GMR device because such step is well known in the art when using a spin-valve element.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pensee T. Do
Patent Examiner
May 26, 2007

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